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**NAVY MEDICINE**  
**BUMED M312 Healthcare Business**

SUPPLEMENTAL HEALTH CARE PROGRAM  
WAIVER SUBMISSION  
STANDARD OPERATING PROCEDURES

## **Table of Contents**

Introduction.....	4
Part 1. Preparing an SHCP Waiver.....	5
1.1 Overview.....	5
1.2 Detail the Exclusion of Identified Care or Service.....	5
1.3 Detail the Patients Clinical History.....	5
1.4 Medical Equipment Items.....	6
1.5 TRICARE Standards of Reliable Evidence.....	6
1.6 Standards of Evidence for Rare Diseases.....	6
1.7 Medical Justification.....	7
1.8 Impact to Fitness for Duty and Readiness.....	7
1.9 Additional Information.....	7
1.10 Endorsements.....	7
Appendix A: SHCP Waiver Process.....	9
Appendix B: SHCP Waiver Letter Format Template.....	11
Appendix C: References.....	14
Appendix C: SHCP Points of Contact.....	15

The purpose of this Standard Operating Procedure (SOP) is to guide Action Officers (AO) assigned to the Navy Bureau of Medicine and Surgery (BUMED) Healthcare Business Branch (M312) on the proper preparation and routing of an SHCP waiver. The ultimate goal is to ensure consistency with waiver processing.

This SOP references other entities and processes. Any changes to these procedures must be first reviewed by the lead analyst and then approved by the BUMED M312 Program Manager (PM). The PM will review and update this document at the end of each fiscal year to incorporate lessons learned and any process improvements.

## **Introduction**

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The SHCP, with specific exceptions discussed in this SOP, pays for private sector care (PSC) received by eligible active duty service members (ADSMs). The SHCP exists under authority of Title 10 United States Code (USC), [10 USC 1074\(c\)](#), and United States Code of Federal Regulations (CFR), [32 CFR 199.16\(a\)\(3\)](#). The use of the SHCP to pay for care referred by MTF providers is governed by Assistant Secretary of Defense (Health Affairs) (ASD(HA)) Policy Memorandum 12-002, "Use of Supplemental Health Care Program Funds for Non-Covered TRICARE Health Care Services and the Waiver Process for ADSMs (February 12, 2012).

- The SHCP is used to pay for PSC for ADSMs. Services that would not have ordinarily been covered under TRICARE policy (including limitations and exclusions) may be authorized for ADSMs in accordance with the terms of a waiver approved by the Director, Defense Health Agency (DHA), at the request of an authorized official of the Uniformed Service concerned.
- An eligible SHCP claim must have a valid authorization for care on file in order to be considered a legitimate referral. Private sector care rendered to an individual who is enrolled to an MTF or civilian PCM does not mean that those services were appropriately authorized. If a claim is received by TRICARE for an ADSM and no authorization is on file, the appropriate Managed Care Support Contractor (MCSC) will inquire with the enrollee's MTF, or the respective Service Point of Contact in the case of ADSMs enrolled in TRICARE Prime Remote, to determine if care was referred and seek a retro-authorization if allowed. The MCSC may also contact the ADSM for follow-up.

## **Preparing an SHCP Waiver**

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1.1 SHCP waivers must be submitted to the Bureau of Medicine and Surgery through their respective Navy Medicine Regional Command. This SOP provides guidance for Navy and Marine Corps ADSMs only. Waiver requests for any non-Sailors or Marines enrolled to MTFs **must** be processed through their specific Service. All requirements from Appendix A must be met before submission to BUMED. Use the waiver format template provided in Appendix B.

- A. Waiver submissions **must** include sufficient medical justification along with the submission of reliable evidence.
- B. Hand written waivers **will not** be accepted.
- C. Waivers **must** be encrypted as they contain protected patient health information (PHI).
- D. Incomplete waivers will be returned.
- E. Waivers **must** receive BUMED endorsement prior to submission to DHA.

1.2 Detail the Exclusion of Identified Care or Service: (citing specific policy), applicable policy letters or TRICARE Manuals (<http://manuals.tricare.osd.mil/Search.aspx>).

- A. Waivers are not permissible if prohibited by Statute (Title 10 USC, Chapter 55, Medical and Dental Care).
- B. TRICARE Policy Manual, Chapter 1, Section 2.1 excludes coverage of treatments, devices, and/or drugs that have not been proven safe and effective according to the hierarchy of reliable evidence per 32 CFR 199.4(g)(15)(i)(C) and 199.2(b).
- C. Off-label use of an FDA-approved device is prohibited and not waiverable per 32 CFR 199.4(g)(15)(ii).
- D. Medical devices not yet FDA-approved, to include FDA-approved for marketing or IDE study protocols, are prohibited and not waiverable per 32 CFR 199.4(g)(15)(i)(A).

1.3 Detail the Patient's Clinical History:

- A. History of present illness/condition (include age, sex, and current military duty).
- B. Previous treatments including medications.
- C. Current medications.
- D. Relevant past medical history.
- E. Results of consultations (include copy of consultation).
- F. Results of relevant laboratory, radiological, and other ancillary studies.
- G. Any duty limitations due to condition.
- H. If photographs can be submitted, include where and when photo was taken.

#### 1.4 Medical Equipment Items:

- A. Include cost of item.
- B. For some medical equipment items medical evidence may not be available or necessary but will need discussion of medical justification. (Appendix A 4.3-6.)

1.5 TRICARE Standards of Reliable Evidence: In order to ensure that ADSMs receive services that meet the standard of care and are proven medically or psychologically necessary and appropriate for the identified condition, 32 CFR 199.2(b)<sup>1</sup> requires that there be reliable evidence stipulating that any drug, device, medical treatment, or procedure supported by the TRICARE benefit must be a nationally accepted medical practice with (in order of relative weight granted to each source)<sup>2</sup>:

- A. Well-controlled studies of clinically meaningful endpoints, published in refereed medical literature.
- B. Published formal technology assessments.
- C. Published reports of national professional medical associations.
- D. Published national medical policy organization positions.
- E. Published reports of national expert opinion organizations.

1.6 For *rare diseases*<sup>3</sup>, TRICARE recognizes that meeting the usual high standard of evidence may not be possible due to the small numbers of patients available to participate in studies. Therefore, rare diseases are held to a slightly less rigorous level of evidence in determining case-by-case support for treatment options.<sup>4</sup> Considerations for evidence for rare diseases are as follows – in order of relative weight to be given to any particular source:

- A. Trials published in refereed medical literature.
- B. Formal technology assessments.
- C. National medical policy organization positions.
- D. National professional associations.
- E. National expert opinion organizations.

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<sup>1</sup> Also included in Chapter 1, Section 2.1 of the TRICARE Policy Manual (TPM) August 2002 edition.

<sup>2</sup> Abstracts, review articles, and letters to the editor are **NOT** considered reliable evidence. Neither are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence, or personal professional opinions. Furthermore, the fact that a provider or a number of providers have elected to adopt a drug, device, or medical treatment or procedure as their personal treatment or procedure of choice / standard of practice is **NOT** an alternative or contribution to reliable evidence.

<sup>3</sup> A rare disease is defined as a condition that affects less than 200,000 Americans.

<sup>4</sup> Even for rare diseases, however, 32 CFR 199.4(g)(15)(ii) requires a determination that a proposed treatment is safe and effective for that disease.

1.7 Medical Justification:

- A. Describe the requested care and anticipated benefit on the ADSM's condition using the reliable evidence submitted as part of Appendix B.
- B. What treatment(s) have been tried and were unsuccessful?
- C. Why is the requested care preferred over current standard treatment? How does it compare in regards to safety and efficacy over current standard treatment?
- D. For medical equipment items, describe why the requested items are medically necessary for ADSM's condition and recovery.
- E. Include applicable ICD-10, CPT, or HCPCS code(s)

1.8 Impact of Requested Medical Service to ADSM's Return to Fitness for Duty and Readiness:

Describe the potential impact of the requested healthcare service on ADSM's fitness for duty and military readiness. A note should also be included if the ADSM has been referred to a Medical Evaluation Board or the Integrated Disability Evaluation System.

1.9 Additional Information:

- A. Is the service member seriously ill or injured? If so, is the member enrolled in the Federal Recovery Care Program?
- B. If the waiver is for a non-cancer clinical trial, does the DoD have a research or partnership agreement with the institution for this clinical trial?
- C. Note and attach the informed consent form for the clinical trial.
- D. Note and attach any documents reflecting Service review.
- E. What costs are covered by the clinical trial?

1.10 Under the authority of 32 CFR 199.4(e)(9) and TRICARE Policy Manual Chapter 4, Section 1.1 Complications (Unfortunate Sequelae) Resulting from Non-covered Surgery or Treatment states that:

- A. "Benefits are available for the otherwise covered treatment of complications resulting from a non-covered surgery or treatment when the complication represents a medical condition separate from the condition that the non-covered treatment or surgery was directed toward, and treatment of the complication is not essentially similar to the non-covered procedure."
- B. "A complication may be considered a separate medical condition when it causes a systemic effect, occurs in a different body system from the non-covered treatment, or is an unexpected complication which is untoward based upon prior clinical experience with the procedure."
- C. Identified exclusions to the above policy are: (1) when the complication occurs in the same body system or the same anatomical area of the non-covered treatment; and (2) when the complication is one that commonly occurs.

1.11 Endorsements: Each SHCP waiver request must contain the appropriate level of endorsement prior to submission.

- A. Specialty Leader: Ensure the appropriate BUMED appointed clinical specialty leader provides input and recommendation along with an endorsement statement.
- B. MTF Commanding Officer (CO) or Other MTF Authorized Official: The MTF CO or authorized designee endorses for “Medical Justification and Impact of Requested Healthcare Service, Medical Equipment Item, or Non-Authorized TRICARE Provider to Service Member’s Return to Duty and Readiness.”
- C. Point of Contact for SHCP Waiver: This is the requesting Provider or Official who initiated the SHCP. Prior to endorsing the SHCP, they must counsel the ADSM on the financial risks of follow-on, non-authorized care. (See Appendix B. Part I).
- D. Navy Medicine Regional Command: Chief Medical Officer or Other Authorized Official.
- E. BUMED Endorsement: Chief Medical Officer or Other Authorized Official.
- F. DHA, Clinical Support Division Endorsement: Senior Medical Director or Other Authorized Official.
- G. Director, DHA or other Authorized Official: Final Approval/Disapproval”

1.12 Next Steps

- A. The estimated time for DHA to return a final disposition is two weeks to six months.
- B. When BUMED receives a dispositioned SHCP waiver from DHA, return it to the NAVMED Regional SHCP Representative within 5 business days.
- C. Retain a copy in the M312 Healthcare Business SHCP Shared Drive folder.

## **APPENDIX A: SHCP Authorization Process**

1. Has the provider been suspended or sanctioned by TRICARE?
  - Yes: Coverage not authorized. No waiver is possible.**
  - No: Please proceed to Question 2**
  
2. Is the requested care prohibited by policy<sup>5</sup>? *For clarification see footnotes below.*
  - Yes: Coverage not authorized. Waiverable at the Director, DHA level.**<sup>6</sup>
  - No: Please proceed to Question 3**
  
3. Is the requested care part of the TRICARE benefit?
  - Yes: Coverage is authorized. Access standards pertain.**
  - No: Please proceed to Question 4**
  
4. Is the requested care medical or dental care<sup>7</sup>? *For clarification see footnotes below.*
  - Yes: Please proceed to Question 5**
  - No: Coverage not authorized. No waiver is possible.**
  
5. Is the requested care prohibited by statute<sup>8</sup>? *For clarification see footnotes below.*
  - Yes: Coverage not authorized. No waiver is possible.**
  - No: Please proceed to Question 6**

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<sup>5</sup> Services prohibited by policy include: (1) Network Chiropractic services per TRICARE Policy Manual: 1.1.38 and 7.18.5, (2) Bariatric surgery per Tricare Policy Manual: 1.1.28 and 4.13.2 as well as NAVMED Policy Memo 07-006, and (3) Acupuncture services when rendered by a non-authorized provider per Tricare Policy Manual 1.1.40.

<sup>6</sup> Applicable only under very unusual and limited circumstances.

<sup>7</sup> The SHCP authorizes purchase of medical and/or dental care for active duty members so long as the service being considered is not "Non-Inherent." 10 USC 1074(c)(1) – for Exercise equipment, including amputee adaptive equipment see 32 CFR 199.4(g)(43)) and the Tricare Operations Manual 5.5; for Gym memberships see 32 CFR 199.4(g) (43) and the Tricare Operations Manual 5.5; for Spas and Hot Tubs see 32 CFR 199.4(g)(44)) and the Tricare Operations Manual 5.5.

<sup>8</sup> Services explicitly prohibited by statute include:

- Elective termination of pregnancy except mother would be endangered if the fetus were carried to term or in a case in which the pregnancy is the result of an act of rape or incest per 10 USC 1093(a), TRICARE Policy Manual 4.18.3.
- Research on human subjects not compliant with requirements of federal statute. 32 CFR 219 , 42 USC 300v-1(b)
- Off-label FDA device use per 32 CFR 199.4(g)(15)(ii)

6. Are ADSMs prohibited by regulation from receiving the requested care<sup>9</sup>?
- Yes: Private elective coverage is prohibited by statute. Coverage neither authorized nor waivable at the Director, DHA level.**<sup>10</sup>
  - No: Please proceed to Question 7**
7. Is the requested care proven safe and effective?<sup>11</sup>
- Yes: Please proceed to Question 8**
  - No: Coverage not authorized. Waivable at the Director, DHA level.**<sup>12</sup>
8. Is the requested care necessary to assure adequate availability of health care services to the member<sup>13</sup>?
- Yes: Coverage not authorized. Waivable at the Director, DHA level.**<sup>14</sup>
  - No: Coverage may be authorized at the discretion of the MTF Commander; access standards may or may not apply. The MCSC or TRO medical director can help determine the advisability of covering this service.**

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<sup>9</sup> ADSMs are not necessarily precluded from obtaining healthcare services that are excluded from the TRICARE benefit by regulation, but the CFR does prohibit services that are not necessary to assure adequate availability of health care services. Examples include: (1) IVF, other non-coital reproductive technologies; (2) elective (not medically necessary) circumcision; (3) reversal of elective sterilization procedure; and (4) cosmetic surgery excepting "correction of minor dermatological blemishes and minor anatomical anomalies".

<sup>10</sup> Upon the request of an authorized official of the uniformed service concerned, to ensure adequate availability of health care services to the ADSM. Applicable only under very unusual and limited circumstances.

<sup>11</sup> As a general rule, the SHCP may be used only to procure care that is safe and effective. Phase II and III clinical trials under the DoD/NCI Cancer Clinical Trials Demonstration may be approved under SHCP, on a case by case basis. Care that may not be approved includes: (1) phase II and III clinical trials outside the TRICARE benefit, (2) compassionate use devices outside the TRICARE benefit, (3) any drug or device that has not yet received pre-market approval from the FDA, (4) phase I clinical trials, and (5) care available only outside the United States.

<sup>12</sup> Applicable only under very unusual and limited circumstances.

<sup>13</sup> Examples of services currently not considered proven safe and effective under TRICARE include: FDA approved devices that are not part of the TRICARE benefit, cranial orthosis for positional plagiocephaly per TPM Chapter 9 Section 3.1, and vagus nerve stimulator for refractory depression per TPM Chapter 4, Section 20.1.

<sup>14</sup> Applicable only under very unusual and limited circumstances.

## **APPENDIX B: SHCP Waiver Letter Template**

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To: Defense Health Agency, Clinical Support Division

From: Name of Requesting Provider, Official, MTF, or other location, Service

Via: Specialty Leader

Navy Medicine Regional Command with oversight of the MTF

Assistant Deputy Chief, Healthcare Operations (M3), Navy Bureau of Medicine and Surgery

Date:

Subject: Request for Deputy Director, Defense Health Agency to Approve the Use of Supplemental Health Care Program Funds for [*name of drug, device, medical equipment, medical treatment or procedure*] in the Care of [*rank/name of Service Member/Beneficiary*]

A. Care Excluded per (*cite applicable policy letter, TRICARE Manual, or Federal Regulation*)

B. Clinical History (as appropriate to support requested service, medical equipment, or non-authorized TRICARE provider)

C. Medical Equipment Items (N/A if not applicable)

D. Unauthorized Facility/Provider (if applicable) N/A

E. 1. Medical Evidence

2. Medical Justification

F. Additional Information (N/A if not applicable)

G. MTF Authorized Official who Counseled ADSM:

I certify that the Active Duty Service Member (ADSM) noted above has been counseled as required by applicable law, regulations and policies, including the point that should a waiver be granted and the treatment remains a non-covered TRICARE benefit, any follow-on care, including care for complications, will not be covered by TRICARE once the ADSM separates or retires, and that the individual may then be financially responsible for the costs of such follow-on care.

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Point of Contact or authorized Official's Rank, Name, Signature and Date

H. Point of Contact (Requesting Provider, Official) Information

1. Name/Rank/Title
2. Clinical Department
3. Facility and Address
4. Phone (work) (cell) .mil email address

I. Specialty Leader Input and Recommendation

- I recommend approval of this waiver as necessary to assure adequate availability of health care to this active duty member.
- I do not recommend submission of this waiver.  
(Do not submit to the Navy Medical Region).

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Specialty leader's Rank, Name, Signature and Date

J. Medical Justification and Impact of Requested Healthcare Service, Medical Equipment Item or Non-Authorized TRICARE Provider to Service Member's Return to Duty and Readiness)

- I recommend approval of this waiver as necessary to assure adequate availability of health care to this active duty member.
- I do not recommend submission of this waiver.  
(Do not submit to the Navy Medical Region).

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MTF Commander or Other Authorized Official's Rank, Name, Signature and Date

K. Navy Medicine Regional Command Endorsement

- I support the submission and approval of this waiver.
- I do not support submission of this waiver.  
(Do not submit to the Navy Bureau of Medicine and Surgery).

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Rank, Name, Chief Medical Officer or Other Authorized Official, Signature and Date

L. BUMED Endorsement:

- I support the submission and approval of this waiver.
- I do not support submission of this waiver.  
(Do not submit to the DHA).

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Rank, Name, Chief Medical Officer or Other Authorized Official, Signature and Date

M. DHA, Clinical Support Division Endorsement:

- I support the submission and approval of this waiver.
- I do not support submission of this waiver. (Do not submit to the DHA).

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Rank, Name, Senior Medical Director or Other Authorized Official, DHA, Clinical Support Division, Signature and Date

N. Director, DHA

- Approve: \_\_\_\_\_ Signature \_\_\_\_\_ Date:
- Disapprove: \_\_\_\_\_ Signature \_\_\_\_\_ Date:
- Other: \_\_\_\_\_ Signature \_\_\_\_\_ Date:

Comments:

## **APPENDIX C: References**

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10 U.S.C. 1074(a)(1) - ADSMs are entitled to medical and dental care in MTFs

10 U.S.C.1074(c)(1) - Using SHCP funds

10 U.S.C. 1074(c)(2)(a) - Care is limited to the TRICARE Prime benefit

32 CFR 199.4 - TRICARE Basic Program benefit

32 CFR 199.16(c) - SHCP medical care coverage for ADSM's.

[32 CFR 199.16\(f\)](#) - Director, DHA SHCP waiver payment process governance.

[TRICARE Operations Manual 6010.56-M](#), SHCP Chapter 17, Sections 1 and 3.

[HA Policy 12-002](#) - SHCP Waiver Process for ADSMs.

[HA Policy 03 March 2009](#) - SHCP Funding for Periodic Physical Examinations (PPE) for Members on the Temporary Disability Retirement List (TDRL).

TRICARE Manuals - <http://manuals.tricare.osd.mil/pages/Default.aspx>

[Health.mil](#) - SHCP

## **APPENDIX D: SHCP Points of Contact**

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### 1. Specified Authorization Staff (SAS)

- DHA  
7700 Arlington Blvd, Suite 5101  
Falls Church, VA 22042-5126
- DHA-Great Lakes  
P.O. Box 886999  
Great Lakes, IL 60088-6999  
Telephone: 1-888-647-6676  
FAX: (847) 688-6460

### 2. Service Project Officers

- Navy/Marine Corps BUMED Healthcare Business (M312)  
7700 Arlington Blvd, Suite 5125 Falls Church, VA 22042-5125  
Unsecured Email: [usn.ncr.bumedfchva.mbx.tricare-claims—waivers@mail.mil](mailto:usn.ncr.bumedfchva.mbx.tricare-claims—waivers@mail.mil)  
*(Please note that this inbox cannot accept encrypted emails. Any incoming encrypted emails will need to be sent through the [AMRDEC Safe Access File Exchange program](#).)*
- Army HQ, USA MEDCOM HP&S, Clinical Services Division  
2748 Worth Road, Suite 10 Fort Sam Houston, TX 78234-6113  
Telephone: (210) 295-7209
- Air Force AFMOA/SGAT  
2261 Hughes Ave, Suite 153 JBSA Lackland, TX 78236-1025  
Unsecured E-mail: [AFMOA.SGAT@us.af.mil](mailto:AFMOA.SGAT@us.af.mil)  
*(Please note that e-mail sent unencrypted can be vulnerable to unauthorized access)*
- United States Coast Guard Health, Safety, and Work-Life Service Center  
Attn: Chief, Medical Administration Division 300 East Main Street, Suite 1000  
Norfolk, VA 23510-9109